The date for filing this response is therefore extended from July 16, 1996 to and including October 16, 1996. If there is any deficiency or surplusage of the fees enclosed for the Extension of Time (fee), please obtain any such deficiency or credit the surplusage to Deposit Account 08-3255 and advise Applicants' Agent.

Applicants also enclose a Petition pursuant to §1.129(a) to Withdraw Final Rejection, together with the fee of $750.00 U.S. funds pursuant to §1.17(r). If there is any deficiency or surplusage of the fees enclosed for the Petition to Withdraw Final Rejection (fee), please obtain any such deficiency or credit the surplusage to Deposit Account 08-3255 and advise Applicants' Agent.

Please enter the following submissions:

IN THE CLAIMS

Please amend the claims as follows:

6. (Fourth Amendment) A method of treating a disease or condition of the skin and exposed tissue comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which consists essentially of administering topically several [a number of] times daily to the site on the mammal of the disease or condition over such period to treat and resolve said disease or

condition [a prolonged period of time] a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient an effective dosage amount of a drug which inhibits prostaglandin synthesis (component [(]1) and an effective dosage amount comprising at least 30-60 mg of a form of hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component [(]2) sufficient to transport the drug (component [(]1) into the skin and/or exposed tissue [(including any scar tissue] at the site of the disease or condition to be treated to block prostaglandin synthesis.

E1 Cntd

8. (Fourth Amendment) The method of Claim 6 wherein the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons and greater than 150,000 daltons.

E2

10. (Fourth Amendment) The method of Claim 9 wherein the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam [IBUPROFEN, PIROXICAM], Propionic Acid derivatives, acetylsalicylic [aceytylsalicylic] acid and Flunixin.

E3

12. (Thrice Amended) The method of Claim 11 wherein component (2) is sodium hyaluronate having a molecular weight less than about 750,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and

E4

component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount and greater than 150,000 daltons.

13. (Thrice Amended) A method of treating basal cell carcinoma which consists essentially of administering several [a number of] times daily topically to the site on the mammal of the basal cell carcinoma over such period to treat and resolve said disease or condition [a prolonged period of time] a non-toxic effective dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient, dosage amount of a non-steroidal anti-inflammatory drug (NSAID) which inhibits prostaglandin synthesis (component 1) and an effective dosage amount comprising [comrising] a form of hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component 2) sufficient to transport the drug (component 1) into the skin and/or exposed tissue[, including any scar tissue,] at the site of the disease or condition to be treated to block prostaglandin synthesis and wherein component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1% [1 1/2%] by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

E4 cont'd

15. (Fifth Amendment) The method of Claim 13 wherein the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof, having a molecular weight less than 750,000 daltons and greater than 150,000 daltons.

E5

16. (Thrice Amended) The method of Claim 13 wherein the [the] NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam [IBUPROFEN, PIROXICAM], Propionic Acid derivatives, acetylsalicylic [aceytylsalicylic] acid and Flunixin.

E5 cntd

17. (Thrice Amended) The method of Claim 13 wherein component (2) is sodium hyaluronate having a molecular weight less than about 750,000 daltons and greater than 150,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

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Please add new claims ~~18-44~~ as follows. The fee of $826.00 U.S. for adding these claims is enclosed. If sufficient funds have been provided, please debit Deposit Account Number 08-3255 for the necessary additional funds and advise Applicants' Agent.

R126 27

E6

~~18.~~ A method of treating a disease or condition of the skin and exposed tissue comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which consists essentially of administering topically several times daily to the site on the mammal of the disease or condition over such period to treat

and resolve said disease or condition a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient an effective dosage amount of a drug which inhibits prostaglandin synthesis (component 1) and an effective dosage amount comprising at least 30-60 mg of a form of hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component 2) sufficient to transport the drug (component 1) into the skin and/or exposed tissue including scar tissue at the site of the disease or condition to be treated to block prostaglandin synthesis, wherein the percent of component 2 in the composition is between 1-3% by weight of the composition and the percent of component 1 which blocks prostaglandin synthesis in the composition is between 1-5% by weight of the composition.

19. The method of Claim 18 wherein the treatment is applied daily for a number of weeks.

20. The method of Claim 18 wherein the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons and greater than 150,000 daltons.

21. The method of Claim 20 wherein the drug is a non-steroidal anti-inflammatory drug (NSAID).

31 22. The method of Claim 21 wherein the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

32 23. The method of Claim 1 wherein component (2) is sodium hyaluronate having a molecular weight less than about 750,000 daltons and greater than 150,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

33 24. A method of treating a disease or condition of the skin and exposed tissue comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which consists essentially of administering topically several times daily to the site on the mammal of the disease or condition over such period to treat and resolve said disease or condition a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient an effective dosage amount of a drug which inhibits prostaglandin synthesis (component 1) and an effective dosage amount comprising at least 10-1000 mg of a form of

hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component 2) sufficient to transport the drug (component 1) into the skin and/or exposed tissue including scar tissue at the site of the disease or condition to be treated to block prostaglandin synthesis, wherein the percent of component 2 in the composition is between 1-3% by weight of the composition and the percent of component 1 which blocks prostaglandin synthesis in the composition is between 1-5% by weight of the composition.

25. The method of Claim 24 wherein the treatment is applied daily for a number of weeks.

26. The method of Claim 24 wherein the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons and greater than 150,000 daltons.

27. The method of Claim 26 wherein the drug is a non-steroidal anti-inflammatory drug (NSAID).

28. The method of Claim 26 wherein the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

29. The method of Claim 27 wherein component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of

the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

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30. The method of Claim 29 wherein component (2) is sodium hyaluronate having a molecular weight less than about 750,000 daltons and greater than 150,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

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31. A method of treating a disease or condition of the skin and exposed tissue comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which consists essentially of administering topically several times daily to the site on the mammal of the disease or condition over such period to treat and resolve said disease or condition a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient an effective dosage amount of a drug which inhibits prostaglandin synthesis (component 1) and an effective dosage amount comprising at least 10-1000 mg of a form of hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component 2) sufficient to transport

the drug (component 1) into the skin and/or exposed tissue including scar tissue at the site of the disease or condition to be treated to block prostaglandin synthesis.

32. The method of Claim 31 wherein the treatment is applied daily for a number of weeks.

33. The method of Claim 31 wherein the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons and greater than 150,000 daltons.

34. The method of Claim 33 wherein the drug is a non-steroidal anti-inflammatory drug (NSAID).

35. The method of Claim 34 wherein the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

36. The method of Claim 34 wherein component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

37. The method of Claim 36 wherein component (2) is sodium hyaluronate having a molecular weight less than about 750,000 daltons and greater than

150,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

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38. A method of treating a disease or condition of the skin and exposed tissue comprising, basal cell carcinoma, the precancerous, often recurrent, actinic keratoses lesions, fungal lesions, "liver" spots and like lesions (found for the most part in the epidermis), squamous cell tumours, metastatic cancer of the breast to the skin, primary and metastatic melanoma in the skin, genital warts (condyloma acuminata), cervical cancer, and HPV (Human Papilloma Virus) including HPV of the cervix, psoriasis (both plaque-type psoriasis and nail bed psoriasis), corns on the feet and hair loss on the head of pregnant women, in a mammal which consists essentially of administering topically several times daily to the site on the mammal of the disease or condition over such period to treat and resolve said disease or condition a non-toxic dosage amount of a composition comprising, in a pharmaceutically acceptable form, pharmaceutical excipients suitable for topical application, a therapeutically effective, to treat and resolve the disease, condition or lesion, non-toxic to the patient an effective dosage amount comprising 20-100 mg of a drug which inhibits prostaglandin synthesis (component 1) and an effective dosage amount comprising at least 30-60 mg of a form of hyaluronic acid selected from the group consisting of hyaluronic acid and pharmaceutically acceptable salts thereof (component 2) sufficient to transport the drug (component 1) into the skin and/or exposed tissue including scar tissue at the site of the disease or condition to be treated to block prostaglandin synthesis.

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39. The method of Claim 38 wherein the treatment is applied daily for a number of weeks.

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40. The method of Claim 38 wherein the form of hyaluronic acid is selected from the group consisting of hyaluronic acid and a pharmaceutically acceptable salt thereof having a molecular weight less than 750,000 daltons and greater than 150,000 daltons.

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41. The method of Claim 40 wherein the drug is a non-steroidal anti-inflammatory drug (NSAID).

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42. The method of Claim 41 wherein the NSAID is selected from the group consisting of diclofenac, indomethacin, naproxen, and (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, Propionic Acid derivatives, acetylsalicylic acid and Flunixin.

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43. The method of Claim 41 wherein component (2) equals or is less than 3% by weight of the dosage amount but equal to or greater than 1 1/2% by weight of the dosage amount and component (1) equals or is less than 5% by weight of the dosage amount but equals to or greater than 1% by weight of the dosage amount.

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44. The method of Claim 43 wherein component (2) is sodium hyaluronate having a molecular weight less than about 750,000 daltons and greater than 150,000 daltons and is in the concentration of 2 1/2% by weight of the dosage amount and component (1) is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.